PCT/JP2003/011631

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 3097WO0P	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP2003/011631	International filing date (*day/month/year*) 11 September 2003 (11.09.2003)	Priority date (*day/month/year*) 13 September 2002 (13.09.2002)
International Patent Classification (IPC) or national classification and IPC C12N 15/12, A61K 31/7088, 38/00, 39/395, 45/00, 48/00, A61P 25/00, 25/14, 25/14, 25/16, 25/28, C07K 16/18, C12Q 1/68, G01N 33/15, 33/50, 33/53, 33/566		
Applicant TAKEDA CHEMICAL INDUSTRIES, LTD.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
14 October 2003 (14.10.2003)	21 April 2004 (21.04.2004)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
[redacted]/JP2003/011631

I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed

☐ the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the drawings:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 1-2, 14, 17-24, 32, 35-40

because:

☒ the said international application, or the said claims Nos. 20-21, 38-39 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

The subject matter of claims 20-21 and 38-39 includes a method of treatment of the human body.

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 1-2, 14, 17-19, 22-24, 32, 35-37,40 are so unclear that no meaningful opinion could be formed *(specify)*:

(See the Supplemental Box)

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 1-2, 14, 17-24, 32, 35-40.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

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IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

☐ restricted the claims.

☐ paid additional fees.

☐ paid additional fees under protest.

☒ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

☐ complied with.

☒ not complied with for the following reasons:

The common matter of claims 3-5, 6-10, 11, 12-13, 15-16, 25-26, 27-29, 30-31 and 33-34 is a protein containing the amino acid sequence which is represented by SEQ. ID. NO: 1.

However, upon investigation, the above claims are not novel, because said protein was described in document WO, 01/38503, A2 (SUGEN, INC.), 31 May, 2001.

As a result, said protein does not extend beyond the scope of prior art. This common matter is not a distinctive technical feature in the sense of PCT Rule 13.2-2.

Therefore, there is no common matter throughout the claims.

Because there is no other common matter that can be considered a distinctive technical feature in the sense of PCT Rule 13.2-2, no technical relationship can be found among these divergent inventions in the sense of PCT Rule 13.

Thus, it is obvious that the subject matter of claims 3-5, 6-10, 11, 12-13, 15-16, 25-26, 27-29, 30-31 and 33-34 do not satisfy the requirement of unity of invention.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☐ all parts.

☒ the parts relating to claims Nos. 3-5

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims		YES
	Claims	3-5	NO
Inventive step (IS)	Claims		YES
	Claims	3-5	NO
Industrial applicability (IA)	Claims	3-5	YES
	Claims		NO

2. Citations and explanations

Document 1:

Claims 3-5

The inventions described in claims 3-5 do not appear to be novel based on document 1 cited in the ISR.

Document 1 describes an antisense polynucleotide complementary to the DNA that encodes the protein containing an identical amino acid sequence as the amino acid sequence represented by SEQ. ID. NO: 1.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box III:

The preventive / therapeutic agent described in claims 1-2 requires obtaining "a protein containing an identical or substantially identical amino acid sequence as the amino acid sequence represented by SEQ. ID. NO: 1, or a compound or salt inhibiting the activity of such protein, a partial peptide of such protein, or a salt of such protein" and it includes preventive / therapeutic drugs containing various compounds that have such inhibiting activity or salts of such compounds.

However, because none of the various compounds having such inhibiting activity or salts of such compounds is specifically described in the specification, the subject matter of claims 1-2 is not sufficiently supported by the specification and is not sufficiently disclosed. Furthermore, in light of the level of technical knowledge at the time of filing, it is entirely unclear which substances are included as said compound or salt thereof in this description and which are not, and thus, the descriptions in claims 1-2 are exceedingly vague.

Therefore, no meaningful preliminary examination can be carried out for the inventions described in claims 1-2.

The same holds true for the inventions set forth as claims 14, 17-19, 22-24, 32, 35-37 and 40.